

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A method for measuring quantitatively or qualitatively an analyte in a whole blood sample, which comprises a reaction step of comprising:

forming a reaction system including a sample containing whole blood, by adding to the whole blood sample a first substance carried by which is immobilized on a solid carrier and specifically binding binds to an analyte contained in the whole blood sample and a second substance which specifically binding binds to the analyte and allowing to allow the analyte to react with the first and second substances to form a complex of first substance-analyte-second substance,

separating the complex, and

detecting the complex to measure quantitatively or qualitatively the analyte in the complex, a measurement step of measuring a formed reaction product,

wherein said reaction system comprises detergent in a concentration range of 0.5 to 5% so that hemolysis is prevented

- (1) the reaction step is performed in a state that blood cells are not disrupted; and
- (2) at least the reaction step is performed in the presence of a sufficient amount of a detergent that does not cause hemolysis, does not inhibit reactions of the analyte with the first and second substances specifically binding to the analyte and can prevent influence on the reaction system of a component existing in the reaction system.

Claim 2 (original): The method according to claim 1, wherein the detergent is selected from the group consisting of polyoxyethylene sorbitan ester type detergents and sulfobetaine type detergents.

Claim 3 (canceled).

Claim 4 (currently amended): The method according to claim 1, wherein the reaction system is formed by mixing the whole blood sample with a whole blood treatment solution comprising detergent and adding the first and second substances to the mixture of the whole blood sample and the whole blood treatment solution sample containing whole blood contains whole blood and a whole blood treatment solution, and the whole blood treatment solution contains a sufficient amount of a detergent that does not cause hemolysis, does not inhibit reactions of the analyte with the first and second substances specifically binding to the analyte and can prevent influence on the reaction system of a component existing in the reaction system when the whole blood treatment solution is mixed with whole blood.

Claim 5 (original): The method according to claim 4, wherein the detergent is selected from the group consisting of polyoxyethylene sorbitan ester type detergents and sulfobetaine type detergents.

Claim 6 (canceled).

Claim 7 (currently amended): The method according to claim 4, wherein the ratio of the whole blood sample and the whole blood treatment solution is in the range of 99:1 to 5:95.

Claim 8 (currently amended): The method according to claim [[4]] 1, wherein the reaction system is formed by adding the first substance to the a whole blood treatment solution comprising detergent and then mixing the whole blood sample with the mixture of the whole blood treatment solution and the first substance, and then adding the second substance to the mixture of the whole blood treatment solution, the first substance, and the whole blood sample further contains the first substance specifically binding to the analyte.

Claim 9 (currently amended): The method according to claim 1, wherein the reaction system is formed by mixing the whole blood sample with a whole blood treatment solution comprising detergent, then adding the first substance to the mixture of the whole blood sample and the whole blood treatment solution, and then adding the second substance to the mixture of the whole blood sample, the whole blood treatment solution, and the first substance step of allowing the analyte to react with the first and second substances comprises a first reaction step of allowing the first substance to react with the sample containing whole blood to form a first reaction product and a second reaction step of allowing the second substance to react with the first reaction product to form a second reaction product.

Claim 10 (previously presented): The method according to claim 1, wherein the second substance is labeled with a labeling substance.

Claim 11 (currently amended): The method according to claim 1, wherein the first and second substances which specifically bind to the analyte are an antigen or an antibody.

Claim 12 (withdrawn): A method for measuring an analyte in whole blood, which comprises:

- (1) a dilution step of diluting whole blood by mixing the whole blood with a whole blood treatment solution;
- (2) a first reaction step of adding a first substance carried by a solid carrier and specifically binding to the analyte to the diluted whole blood and allowing them to react to form a first reaction product in a reaction system;
- (3) a first separation step of separating the first reaction product formed in the first reaction step from the reaction system;
- (4) a second reaction step of adding a second substance specifically binding to the analyte to the separated first reaction product and allowing them to react to form a second reaction product in a reaction system;
- (5) a second separation step of separating the second reaction product formed in the second reaction step from the reaction system; and
- (6) a measurement step of measuring the separated second reaction product, wherein the whole blood treatment solution contains a sufficient amount of detergent that does not cause hemolysis, does not inhibit reactions of the analyte with the first and second substances, and can prevent influence on the reaction system of a component existing in the reaction system in each step when the solution is mixed with the whole blood.

Claim 13 (withdrawn): The method according to claim 12, wherein the second substance is labeled with a labeling substance.

Claim 14 (withdrawn): The method according to claim 13, wherein the first and second substances specifically binding to the analyte are antigen or antibody.

Claim 15 (currently amended): A reagent kit for measuring an analyte in a whole blood sample, which comprises a first substance ~~carried by~~ which is immobilized on a solid carrier and specifically binding binds to the analyte, a second substance which specifically binding binds to the analyte and a ~~detergent which does not cause hemolysis and does not inhibit reactions of the analyte with the first substance and the second substance~~ whole blood treatment solution which comprises detergent and is adjusted so that detergent concentration is 0.5 to 5% when ~~it~~ the solution is ~~mixed added to~~ with the whole blood sample.

Claim 16 (canceled).